WHAT'S HAPPENING WEDNESDAY

Kansas Immunization Program

November 3rd, 2021

VFC Consultant On-Call

The Consultant On-Call can be reached Monday—Friday, 8 a.m.—5 p.m. at 785-296-5592.





Hello All! As you know, November is going to be a very busy month. As I write this article, the Advisory Committee on Immunization Practices (ACIP) is meeting to discuss whether or not to recommend Pfizer's COVID-19 vaccine for those 5-11 years of age.

Things are constantly changing in the pandemic response, which can make it very difficult to keep up-to-date with the current recommendations and guidance. In this edition of What's Happening Wednesday (WHW) you will find links to some very helpful resources. We will continue to communicate with providers and other stakeholders as changes are made.

Don't hesitate to reach out to the Kansas Immunization Program (KIP) for assistance with clinical considerations, resources to assist with local response, vaccine ordering, HL7 onboarding, etc. The best ways to contact KIP include:

<u>Kdhe.Vaccine@ks.gov</u> — COVID-19 and VFC orders.

Kdhe.COVIDEnrollment@ks.gov—
Provider enrollment

<u>Kdhe.IMMOnboarding@ks.gov</u>—KSWebIZ onboarding

Kdhe.ImmunizationRegistry@ks.gov or 785-559-4227 —KSWebIZ questions and training

Consultant On-Call —785-296-5592

<u>Immunization Program Staff</u>—contact information

Even though the ACIP is discussing Pfizer's COVID-19 vaccine for use in 5-11 year old's, on November 3rd they will be discussing and voting on other non-COVID -19 issues, including Hepatitis vaccines, Immunization schedules, Orthopoxviruses vaccines, and Ebola vaccine. The agenda for the meeting can be found by clicking on the link: https://www.cdc.gov/vaccines/acip/meetings/agenda-archive.html and the link to watch the meeting is: https://video.ibm.com/channel/VWBXKBR8af4

The agenda for the meeting on November 3rd is a good reminder that the pandemic is not the only issue for us to monitor. Other vaccine preventable diseases are very real and still out there in communities. Remain vigilant and work to get infants, children, adolescents, and adults vaccinated according to CDC Immunization Schedules. As always, thank you for all your hard work! You are very appreciated!

Chief Chat

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COVID-19 guidance changes very quickly and keeping up can feel like a fulltime job. Below you will find websites you can bookmark for quick reference as guidance is updated. The Centers for Disease Control and Prevention's (CDC) Interim Clinical Considerations for Use of COVID-19 Vaccinations webpage includes COVID-19 vaccination and booster recommendations, what to do if a vaccine administration error occurs, triaging patients with contraindications and precautions, and guidance for patients who have received a vaccine outside of the United States. This is just a small part of the information that can be found on this page.

The Moderna COVID-19 Vaccine website provides the latest information and guidance from Moderna. Be sure to frequently check the Moderna Vial Expiration Look-Up as expiration dates are continuing to change as new vaccine stability data is reviewed. With the Moderna COVID-19 Vaccine booster dosage of 0.25 mL verses the primary series dosage of 0.50 mL, there have been a lot of questions regarding the number of doses in a vial, how to add additional doses beyond 10 or 14 doses in KSWebIZ, and providers guidance on the number of doses to waste depending on primary series or booster doses given. You will find answers to these questions as well as many other documents and guidance on the KDHE Kansasvaccine.gov website.

The <u>Pfizer COVID-19 Vaccine</u> website provides the latest information and guidance from Pfizer. Be sure to review the new pediatric guidance frequently once the vaccine is approved by the Advisory Committee on Immunization Practices (ACIP). Also, please take note that the Food and Drug Administration (FDA) authorized an extension of the Pfizer "purple cap" printed expiration date in August 2021. The most current expiration dates can be found in the <u>Emergency Use Authorization (EUA) for Healthcare Providers</u>.

The <u>Johnson and Johnson's Janssen COVID-19 Vaccine</u> website provides the latest information and guidance from Johnson and Johnson. Be sure, as with other COVID-19

vaccines, to check the <u>Expiry Checker</u> as expiration dates may change as stability studies are reviewed.

Booster doses can be very confusing, especially when dealing with 3 different vaccines, some with different formulations. Be sure to check, double check, and triple check the vaccine, and dosing. Does the vaccine need to be mixed? Is the dosing a full or half dose? What interval should the dose be given? What is the beyond use date (BUD) for each specific vaccine once the vial has been punctured? The Kansas
Department of Health and Environment (KDHE) website has guidance on booster doses, vaccine storage guidance, vaccine wastage and reporting to KSWebIZ as well as many other documents to assist with your COVID-19 vaccination efforts.

Employment Opportunities:

The KDHE Bureau of Disease Control and Prevention is seeking qualified candidates to fill multiple positions in our Immunizations, STI/HIV, and Infectious Disease Management sections. Positions available include nurses, administrative staff, and health educators. Check out the State Employment Center (SEC) for available positions. Don't see what your looking for? Keep checking! New positions are posted regularly!

The Kansas Immunization Program has the following openings listed on <u>Careers (ks.gov)</u>:

Mobile Vaccine and Testing Nurse

Vaccines for Children Program Coordinator

Regional Immunization Consultants (Adult Program)



Introductions and Goodbyes

We would like to take a moment to introduce you to a couple of new Kansas Immunization Program (KIP) staff.



Melody Couper is the new Vaccines for Children (VFC) North Central Regional Immunization Consultant. Melody can be reached at 785-471-0083 or at Melody.Couper@ks.gov.



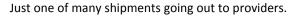
Laura Hageman has joined the KIP as one of the Adult Immunization Regional Consultants. Laura can be reached at 785-471-0095 or at Laura.Hageman@ks.gov

It is with sadness that we say goodbye to Suzanne Proctor, Adult Immunization Program Coordinator, and Susan Smith, South Central VFC Regional Immunization Consultant. In their absence, please email KDHE.vaccine@ks.gov or call the Regional Immunization Consultant On-call at 785-296-5592.



Thank you to our COVID-19 vaccine redistribution team for countless hours of repacking and shipping COVID-19 vaccine! For those of you who have not had the opportunity to see our team in action, we would like to share a few pictures. Thank you for your understanding when we are not as quick to respond as we would like to be.











The warehouse that used to be our Bureau...

Pfizer Pediatric Vaccine Rollout

The FDA has approved Emergency Use Authorization (EUA) of Pfizer's pediatric COVID-19 vaccine for use in children 5 to 11 years of age. The CDC's Advisory Committee on Immunization Practices (ACIP) will be meeting November 2nd to discuss the recommendations made by the FDA. If the ACIP recommends Pfizer's COVID-19 vaccine for use in children 5-11 years of age, the CDC Director will then consider the recommendations and possibly approve as recommended. Please note that vaccination of those 5-11 years of age with Pfizer's COVID-19 vaccine cannot begin until the CDC Director makes the final approval.

In anticipation of the EUA authorization approval by CDC, the KIP surveyed providers to determine who wanted to pre-order 300 or greater doses of vaccine. Due to the limited number of doses available, pre-ordered vaccine will be prioritized based on need. Beginning Wednesday, November 10th, vaccine can be ordered through the routine process. All vaccine deliveries will occur according to the schedule below. Wave 1 deliveries will include doses requested through the pre-order process and subsequent orders will be delivered during Wave 2 and 3, according to vaccine availability.

Delivery Estimates are as follow:

Wave 1 orders will deliver between one (1) and five (5) business days after EUA issuance. Wave 2 deliveries will commence immediately after Wave 1 deliveries are processed. Wave 2 orders will deliver three (2) to seven (7) days after EUA issuance. Wave 3 orders will deliver five (5) to nine (9) days after EUA issuance.

To place and orders, providers should complete the survey found at: https://www.surveymonkey.com/r/3QY82P6

Information, including videos on storage and handling - https://www.cvdvaccine-us.com/

KSWebIZ Helpdesk

KSWebIZ will be undergoing an upgrade to version 21.10 of the application. The system will be down from 5:00 pm – 10:00 pm on Thursday, November 11, 2021 while the upgrade is being performed. Any HL7 messages received during this time will be placed in a que until the upgrade is complete and then released.

A few notable changes include the Recommender 1.7.2 which will now recommend a 3rd dose of Covid-19 to patients that have the Immunocompromised precaution/contraindication on their record. When searching for a patient with the name listed in the Alias section of the demographics screen along with their date of birth should return with the expected results.

A document describing the new features and updates to the application is available on KSWebIZ. The document is titled **KSWebIZ 21.10 Release Contents** and can be found in the **News** section or the **Reports** tab under the **Documents** section.

Tuberculosis Tid-Bit

The Epitrax staff have been very busy lately working on some Epitrax updates. The Tuberculosis (TB) Program would like to provide the following guidance on a few required and frequently used fields within a TB case. Some of these fields apply only to active TB cases, while others apply to Latent Tuberculosis Infection (LTBI). The tables below list the field name and tab on which the field is found, the options for completing the field, and the TB definitions/use cases for the provided options.

We are asking everyone to utilize these tables when entering data into TB cases for uniformity and documentation clarity. If you have any questions or concerns, please reach out to Kimberly (<u>Kimberly.d.winans@ks.gov</u>; 785-296-0739) or Lisa (<u>lisa.edgerton-johnston@ks.gov</u>; 785-296-5589) for assistance.

Outcome-Encounters Tab				
Outcome Status**	TB Definition	Example/Explanation		
Email Monitoring Completed	N/A to TB Investigations	Not to be used in TB investigations. Email is not a sufficient form of monitoring.		
Follow- up/Monitoring Interview Completed	DOT monitoring Follow-up telephone check-in	e.g. patient is seen for DOT appointment regardless of treatment type, telephone contact with patient to remind of upcoming appointment, assess medication tolerance, follow-up for missed appointments		
Initial Interview Completed	Initial TB appointment Contact investigation interviews	e.g. initial TB evaluation appointment regardless of treatment type, encounter with contact of index case to notify of exposure		
Left Message/No Answer	Unanswered telephone calls Mailed letters pending response Drive by contact attempts with no response	Clearly document if voicemail was left or not (if not, explain why e.g. no voicemail set up, mailbox full etc.) Mailed letters best practice sent via certified mail requiring documented receipt (i.e. signature) by patient/guardian		
Other/Completed	Case is closed Encounter does not fit elsewhere	e.g. final case entry stating case has been reviewed and is ready to be closed; other encounters not elsewhere described		

	Outcome-Encounters Tab					
Outcome Status**	TB Definition	Example/Explanation				
Refusal/Declined Interview	Contacts to Active TB that refuse evaluation LTBI treatment refusals	e.g. no response from patient/guardian for >2 weeks post certified letter receipt; staff informed patient is not in residence at listed address during drive by attempt; patient/guardian refusal for treatment and/or evaluation – verbal refusal or signed (best practice is signed refusal)				
Scheduled Interview	Patient is scheduled for future appointment, but has not yet been seen in clinic Contact to Active TB has been scheduled for evaluation	e.g. patient interview or appointment is scheduled after hospital discharge; initial telephone contact with patient to request evaluation (may be patient or LHD initiated)				
Testing Assessment Completed	Evaluation of contacts	e.g. educating contact to risk of TB exposure and providing testing both immediately after exposure and 8 weeks later				
Treatment Assessment Completed	LTBI treatment initiation and follow-up conversations Initial Active TB medication education & monthly nursing assessments	e.g. educating patient to anti-TB treatment including medications, side effects, adverse events; any medication/treatment monthly nursing assessments regardless of treatment type				

^{**}All outcome status options have been listed in this table and should be utilized according to the definitions provided**

Tuberculosis Tid-Bit

Contact Disposition Column Contacts Toh				
Contact Disposition Column – Contacts Tab				
Contact Disposition**	TB Definition	Example/Explanation		
Infected, brought to treatment	Confirmed LTBI or TB disease, treatment initiated	Disposition applies to treatment start only; treatment completion statuses are updated in contact LTBI/TB Disease morbidity event		
Refused preventative treatment	Confirmed LTBI or TB disease, treatment NOT initiated	e.g. patients that complete testing, but do not return to begin treatment or sign refusal of treatment		
Not Infected	Negative LTBI or TB disease testing/assessment after at least 8 weeks post exposure	Only applicable after all follow-up testing has completed		
Located, refused exam and/or treatment	Contacted and informed of exposure, refused testing/follow-up	e.g. patients that do not respond to phone calls/letters		
Unable to locate	Unable to locate or contact to inform of exposure	e.g. insufficient information to contact patient or inaccurate contact information		
Mother/family refusal	Parent/Guardian informed of risk to minor, refused testing/follow-up	e.g. minors evaluated by private physicians and parents refuse testing/window treatment through local public health		
Lost to Follow-up	Unable to locate/contact AFTER testing/treatment has begun	e.g. patient gets first test after exposure, but does not return/respond to contact attempts for 8-week follow-up		
Testing/Treatment Recommended	Confirmed LTBI or TB disease, patient has not yet agreed to treatment	e.g. patient wishes to speak with PCP or "think about it" prior to accepting treatment		
Moved	Patient has moved to another county/area WITHIN Kansas	e.g. patient moves from Wichita to Dodge City and requires follow up by a different jurisdiction		
Out of jurisdiction	Patient has moved OUTSIDE Kansas and requires Interjurisdictional Notification (IJN) to complete follow-up care	e.g. Patient moved from Pittsburg, KS to Joplin, MO, IJN must be sent to Missouri to complete patient follow-up		
Previously treated for this infection	Patient reports treatment for active TB or LTBI in the past and has been evaluated and cleared of active TB disease	e.g. patient received treatment in birth country for LTBI prior to exposure in US **Prior treatment records are requested but NOT required**		

^{**}Not all contact disposition options provided in Epitrax have been listed in this table. Please utilize only those contact dispositions listed above for TB cases unless instructed otherwise by the TB Health Educator or TB Nurse Consultant**

Combook Time Column Combook Tel				
Contact Type**	Contact Type Column – C TB Definition	Example/Explanation		
Adult Household	Any individual over 18 years of age sharing residence with index case	Does NOT have to be a family relation		
Infant	Any individual 5 years of age and under	Does NOT have to be a family relation		
Household	Any individual greater than 5 but less than 18 years of age sharing residence with index case	Does NOT have to be a family relation		
Non-household Family	Any direct relative of index case that does NOT share residence with index case	e.g. grandparents, aunts, uncles, cousins, nieces, nephews etc.		
School/Daycare	Any individual attending school/daycare or related activities with index case OR any individual exposed through repeated index case presence at school/daycare facility	e.g. attends after school activities with index case, shares dorm/communal living space with index case, attends collegiate activities/classes with index case; index case is parent of child attending school/daycare facility, index case volunteers frequently at school/daycare events		
Work	Any individual exposed as a result of the index case's occupation	e.g. works with/near index case, index case performs services in private homes, exposure through employee common areas (i.e. breakrooms, prayer rooms, etc.)		
Social	Any individual exposed outside of shared residence, family, work, or school	e.g. church, support groups, sports teams etc.		

^{**}Not all contact type options offered in Epitrax have been listed in this table. Please utilize only those contact types listed above for TB cases unless instructed otherwise by the TB Health Educator or TB Nurse Consultant**

Pfizer COVID Webinar

Pfizer Vaccines US Medical Affairs will be hosting Immunization Site Training Sessions for All Providers on the Storage, Handling, & Administration for Current & Potential New Formulations of our COVID-19 vaccine (with our partner BioNTech).

These sessions will be **updated** to reflect new information and changes that evolve. Such updates will be identified at the start of each session and further explained during each presentation. Please click on the links below to join the sessions at the designated times. *

Date & Time	Password
Attendee link – October 27 – 12 PM ET	7c2gZCqcSz8
Attendee link – October 28 – 12 PM ET	9ywEun8Mjs7
Attendee link – October 29 – 12 PM ET	cnRBrmGr324
Attendee link – November 1 – 5 PM ET	g9ZmgHaip32
Attendee link – November 2 – 5 PM ET	sJDZQERp325
Attendee link – November 3 – 12 PM ET	82qdN3PppPp
Attendee link – November 4 – 12 PM ET	Y4ZkXdh2bz7
Attendee link – November 5 – 12 PM ET	rJSpNPts332

^{*}Weblinks for future training sessions will provided at a later date.

<u>Before administration of the vaccine, please see full Prescribing Information (16+ years of age)</u> and <u>EUA Fact Sheet for Vaccination Providers</u> (12+ years of age).

Moderna COVID Webinar

Join Moderna for a webinar for vaccination providers to learn more about the Moderna COVID-19 Vaccine booster dose, which has been authorized for emergency use in the United States. There will be no continuing education offered for this webinar. Please register at the link below for one of our available sessions.

Webinar: Important updates on the mRNA-1273 50 μ g Booster Dose Thursday, October 28th at 12pm ET – Register here for Oct 28 Thursday, November 4th at 3pm ET – Register here for Nov 4 Thursday, November 11th at 12pm ET – Register here for Nov 11

Attached to this email is the updated <u>FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)</u>, FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION (revised October 2021), EUA Letter Of Authorization, and Dear Healthcare Provider Letter regarding the Moderna COVID-19 Vaccine Booster Dose.

EUA Information

The Moderna COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated, or the authorization is revoked sooner.

Moderna Call Center

The Moderna Call Center is available from 8am to 8pm EST, Monday through Friday, and can be reached at 1-866-MODERNA (1-866-663-3762).

AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. Moderna COVID-19 Vaccine is investigational and not approved by FDA.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.

Warnings and Precautions

Management of Acute Allergic Reactions: Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis: Post marketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The CDC has published considerations related to myocarditis and

pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope (fainting): May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

Limitations of Vaccine Effectiveness: The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions reported in clinical trials following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, erythema at the injection site, and rash.

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Reporting Adverse Events and Vaccine Administration Errors
The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event
- serious adverse events (irrespective of attribution to vaccination)
- cases of Multisystem Inflammatory Syndrome (MIS) in adults cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. Reports should include the words "Moderna COVID- 19 Vaccine EUA" in the description section of the report.

Report to ModernaTX, Inc. by calling 1-866-MODERNA (1-866-663-3762) or provide a copy of the VAERS form by faxing 1-866-599-1342 or emailing ModernaPV@modernatx.com.

Pregnancy and Lactation

Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

For more information please see <u>Fact Sheet for Healthcare Providers</u>
<u>Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information, EUA Letter of Authorization and Dear HCP Letter.</u>